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5100 Paint Branch Parkway
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M-b-353
Supplement 1

October 31, 2008

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch/Milk Safety Team (HFS-316)

SUBJECT: Tuchenhagen Flow Components, LLC PMO Varivent® Mixproof Valve Type M_O**B** (06) Valve Vent Cavity Cleaning Option

This memorandum is a supplement to M-b-353 (Tuchenhagen Varivent® Mixproof Valve Type M_O (06) Valve Vent Cavity Cleaning Option), which was issued April 10, 2007. This Supplement is for the addition of an equipment redesign, which covers four (4) main valve design areas:

A. The addition of a Balancer Cleaning Device (Valve Nomenclature is updated to PMO Varivent® Mixproof Valve Type M_OB (06)).

   Please see the attached Balancer Cleaning Cut Sheet, which shows a more detailed drawing of the Balancer Cleaning device as well as the PMO M_OB (06) Spare Parts Drawing and List.

B. The addition of a six (6) inch OD valve size (Complete Size range of Type M_OB (06) valve will be 1.5” OD, 2” OD, 2.5” OD, 3” OD, 4” OD and 6” OD).

   The design of the 6" OD PMO Varivent® Mixproof Valve is similar to the 1.5”-4" mixproof valves previously reviewed for M-b 353. Please see the attached vent cavity diagram and table. The cross sectional area (area star) of the outlet of the vent cavity is greater than 100 % of the inlet pipe cross-section area.

   The testing protocol reference PMO Varivent® Mixproof Valve Type M_O (06), issued April 10, 2007 in M-b-353 is on page 6 of M-b-353 and is also the identical test protocol for the six (6) inch valve.

C. Acceptance of Alternative Valve Control Module Options, as follows :

a. T.VIS M-1 Control Module with Device Net Adapter Module;
b. T.VIS M-1 Control Module with AS-Interface Adapter Module;
c. T.VIS M-1 Control Module with AC-Interface Adapter Module;
d. Control Module Type S with AS-Interface Module;
e. Control Module Type S with Device Net Module;
f. Control Module Type S with 3-wire 24 V DC Interface Module; and
g. Control Module Type S with AC voltage Interface Module.

The above mentioned alternative control modules act to convert the valve proximity switch input and solenoid valve output discrete signals into serial bus signal information to be communicated over 1 cable to the CIP PLC or CIP Process Computer. The interface hardware in the above-listed alternative control modules will allow networking capability and will be part of the Automated Fail-Safe Control System, which shall comply with applicable provisions of Appendix H. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade “A” Public Health Controls of the Grade “A” Pasteurized Milk Ordinance (PMO).

D. The removal of the Maximum Seat Lift Time

The 10 second maximum seat lift time was chosen arbitrarily based on the various parameters of the Ohio State University pilot test of the M_O (06) valve. All M_O (06) valve testing showed that at any time during an upper or lower seat lift operation and at any CIP line pressure up to 145 psi, the design of the M_O (06) valve is such that a vacuum condition will occur in the vent cavity and that the length seat lift time will not at all influence the generation of this vacuum condition.

In accordance with M-I-00-2, *Milk and Milk Product Equipment-A Guide for Evaluating Construction*, FDA’s Atlantic Midwest Dairy Equipment Review Committee (AMDERC) and CFSAN’s Dairy and Egg Branch/Milk Safety Team have evaluated and validated the technical information submitted by AMDERC.

When constructed, installed, operated and maintained as outlined in the instructions of the manufacturer’s Operating Instructions, Issue 2008-10-Revison 2, the PMO Varivent® Mixproof Valve M_OB (06) has been found to comply with the PMO.

The technical information that was reviewed addressing the PMO Varivent® Mixproof Valve M_OB (06) constitutes the AMDERC's Engineering Design and Technical Construction File (EDTCF). The material in the EDTCF is the property of the manufacturer and may be shown at their discretion.

For additional information regarding this equipment, please contact:

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FDA's review and acceptance of this piece of equipment does not constitute FDA endorsement or approval. Any representation on a label or in printed literature citing or indicating as "FDA Approved" is false and misleading.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will also be available on the FDA Web Site at http://www.cfsan.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to Robert.Hennes@ fda.hhs.gov.

/ss/

Donald R Goldsmith
FDA Regional Dairy Specialist

/ss/

CAPT Robert Hennes
FDA/MST Milk Sanitation Officer

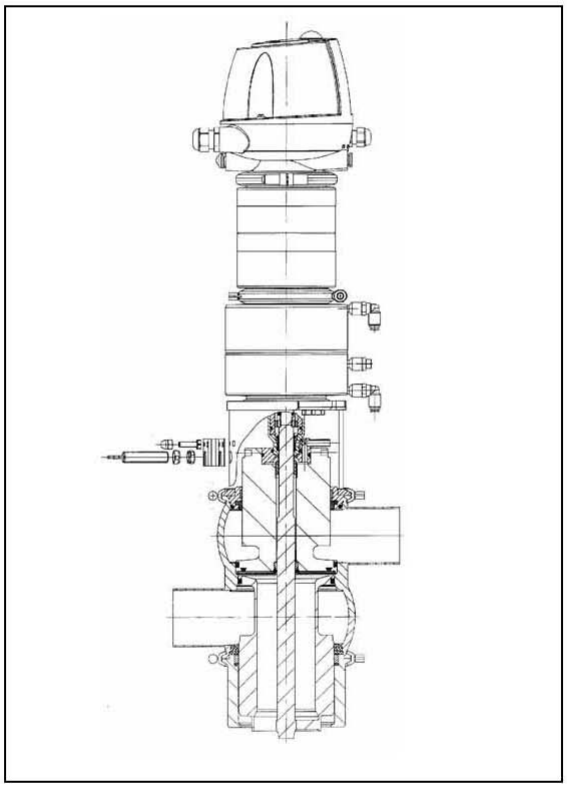
Attachments:

Cover Page, Operating Instructions-Double-seat Mixproof Valve M_O (06), Issue 2008-10-Revison 2
Balancer Cleaning Device Cut Sheet
Cover Page, Operating Instructions-Control Module T.VIS® M-1 for PMO Valve Type M_OB (06), Issue 2008-10-Revision 13
Cover Page, Operating Instructions-Varivent Control Module Type S for PMO Valve Type M_OB (06), Issue 2008-10-Revision 5

Operating Instructions

VARIVENT®

Double-seat Mixproof Valve M_OB (06)



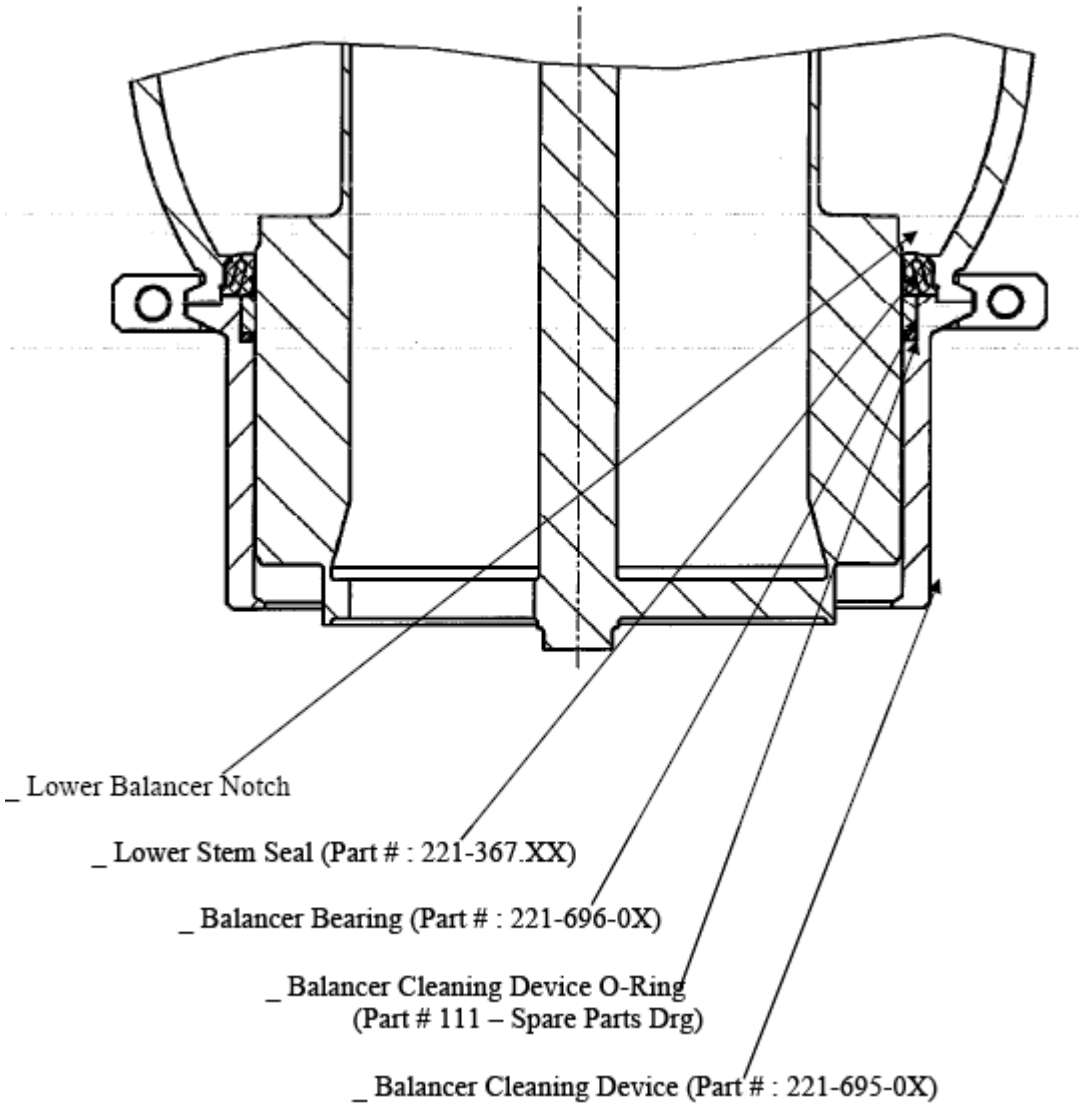
24/7 PMO VALVE NON-STOP PRODUCTION

Issue 2008-10 / Revision 2
Valve code ending ...B/06
Part no. 430-466E
English

Process Equipment
Tuchenhagen

Tuchenhagen PMO Varient® Mixproof Type M_OB (06) Valve

Balancer Cleaning Device Cut Sheet

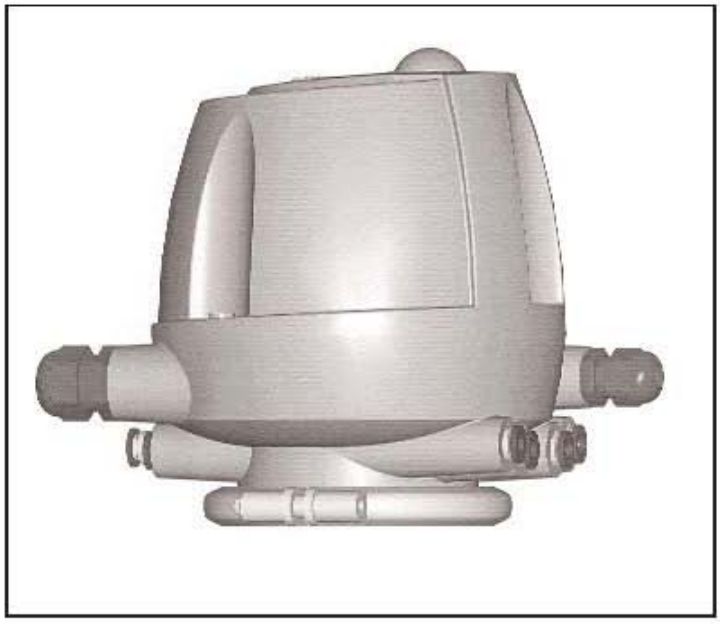


NOTE: Typical configuration for all M_OB (06) valve sizes

Operating Instructions

Control Module T.VIS® M-1

for PMO Valve Type M_OB (06)

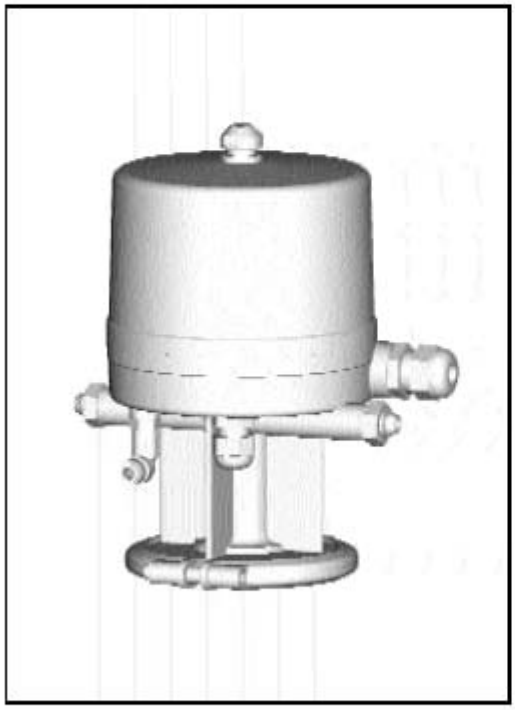


Issue 2008-10 · Revision 13
Part no. 430-398-US
English

Operating Instructions

VARIVENT® Control Module Type S

for PMO Valve Type M_OB (06)



Issue 2008-10 · Revision 5
Part no. 430-209-US
English